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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,649	03/30/2001	Steven M. Ruben	PZ012P1C2	6561

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HUMAN GENOME SCIENCES INC
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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	4

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/820,649	RUBEN ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

This application contains claims directed to the following patentably distinct species of the claimed invention: the DNA and protein sequences associated with each of gene 1 through gene 83 as set forth in table 1 of the specification, see pages 127-138. Applicant is required to elect one (1) of the gene sequences set forth in table 1 and the corresponding nucleotide or amino acid sequence (SEQ ID NO:X or SEQ ID NO:Y, respectively). SEQ ID X is directed to polynucleotides having SEQ ID NO: 11 to SEQ ID NO: 101 as set forth in Table 1. SEQ ID NO: Y is directed to amino acids having SEQ ID NO: 102 to SEQ ID NO: 192. SEQ IDs 11-101 encode SEQ IDs 102-192 respectively. Each of the DNAs and encoded polypeptides have differing structure and function and therefore do not form a proper Markush group. Therefore, each sequence will be placed in its own group because each sequence is patentably distinct one from the other.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Groups 1-91	Claims 1-10, 14, 15 and 21, drawn to an isolated nucleic acid having SEQ ID NO: 11-101 sequence, encoding a polypeptide of SEQ ID NO: 102-192 respectively; recombinant method; vector and host cells, class 435, subclass 69.1.
II. Groups 92-182	Claims 11, 12 and 16, drawn to a protein having SEQ ID NO: 102-192 sequence, class 530, subclass 350.

III. Groups 183-273 Claim 13, drawn to an antibody specific to polypeptide of SEQ ID NO: 102-192, class 530, subclass 388.1.

IV. Groups 274-364 Claim 17, drawn to a gene therapy method using polypeptide sequence of SEQ ID NO: 102-192, class 514, subclass 44.

V. Groups 365-455 Claim 18, drawn to a method of diagnosing using polynucleotides of SEQ ID NO: 11-101, class 435, subclass 6.

VI. Groups 456-546 Claim 19, drawn to a method of diagnosing using a polypeptides of SEQ ID NO: 102-192, class 514, subclass 12.

VII. Groups 547-637 Claims 20, drawn to a method of identifying a binding partner using polypeptide of SEQ ID NO: 102-192, class 435, subclass 7.8.

VIII.Groups 638-728 Claim 22, drawn to a method of identifying an activity using polynucleotides of SEQ ID NO: 11-101, class 436, subclass 501.

IX. Groups 729-819 Claim 23, drawn to a binding partner specific to polypeptides of SEQ ID NO: 102-192, class 435, subclass 7.8.

X. Groups 820-910 Claim 24, drawn to a method of gene therapy using polynucleotides of SEQ ID NO: 11-101, class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The DNA of group I is related to the protein of group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the

specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

The DNA of group I and the antibody of group III are related by virtue of the protein that is encoded by the DNA and necessary for the production of the antibody. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

Inventions I and V, VIII, X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the DNA can be used on other, materially distinct processes, such as in methods for the recombinant production of a protein product or in nucleic acid hybridization assays, for example. Therefore, the inventions are distinct.

Inventions I and IV, VI, VII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different inventions are directed to processes whose end results are materially distinct from the recombinant process of invention I. The results of the processes are directed to different ends. Therefore, the inventions are distinct.

The protein of group II is related to the antibody of group III by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions. Therefore, the inventions are distinct.

Inventions II and V, VIII, X are unrelated. In the instant case, the protein of group II is not used in the gene therapy method of group X, the method of diagnosis of group V or the method of identifying an activity of group VIII. Therefore, the inventions are distinct.

Inventions II and IV, VI, VII, IX are related as product and process of use. In the instant case, the protein of group II can be used in other materially distinct processes from those set forth in groups VI, VI, VII and IX, such as the immunization of a mammal for the production and isolation of antibodies, for example. Therefore, the inventions are distinct.

Inventions III and IV-VIII, X are unrelated. In the instant case, the antibody of group III is not used in any of the methods of groups IV-VIII and X. Therefore, the inventions are distinct.

Inventions III and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the

antibody of group III can be made in other materially distinct processes, such as the immunization of a mammal, for example. The products of claim 23 encompass non-proteinaceous ligands structurally and chemically distinct from the antibody of group III. Therefore, the inventions are distinct.

Inventions IV-VIII and X are unrelated, each to the other. In the instant case, each of the methods employs a different mode of operation from each of the methods of groups IV-VIII and X each is directed to a different effect. Therefore, the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Mark Hyman on June 9, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

Rita Mitra, Ph. D.
July 8, 2003

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